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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,266	04/05/2001	James G. Skakoon	723.041US1	4355
21186	7590	04/26/2005	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402-0938			JUNG, WILLIAM C.	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 04/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,266

Applicant(s)

SKAKOON ET AL.

Examiner

William Jung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5 . 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-14 and 16-32 are rejected under 35 U.S.C. 102(a) as being anticipated by *Truwit* (US 5,993,463).

Claims 1, 11-13, 16-18, 21, 22-24, 27, 29, 30, 32: Truwit anticipates of all claimed invention in claims 1, 11-13, 16-18, 21, 22-24, 27, 29, 30, 32. Truwit discloses of trajectory guidance system and method where the surgical instrument is guided remotely by a surgeon through introducer device consisting of guide unit, holder assembly detachably housing the medical or surgical device. In addition, Truwit's device is MR compatible, i.e., the device is designed to be place in the MRI system (col. 3, line 30 – col. 5, line35; col. 14, lines 33-62; col. 15, lines 23-50; col. 16, line 60 – col. 17, line 27). Truwit also anticipates that the control of the trajectory system is calibrated by the computer system to align the introducer accurately (col. 24, lines 8-23).

Claims 2 and 26: Truwit discloses of the above introducer device where it consists of linear motion along a sliding tower or advancement sleeve 3742 as shown in figure 37 (col. 17, lines 28-67).

Claims 3, 4, 14, 25, 28, and 31: Truwit discloses of controlling of the trajectory guiding device described above where the control member 3002 is attached to the guidance unit 3001 as

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shown in figure 30. Further more, as shown in figure 34, the control mechanism includes rotatable wheel 3450, which is connected to the guidance unit 3001 via cable (pull and push mechanism).

Claims 5 and 6: Truwit discloses of the above introducer device where the body of the guide unit includes hole n place to pass the primary medical or surgical device through the assembly along the range of motion as shown in figure 37 (col. 18, lines 8-26).

Claims 7-9: Truwit discloses of the above introducer device where the locking member 3400 affixes the guide member 3300 in a set place with the locking mechanism where it includes incremental changes are made/control by marker cap 3602.

Claims 10, 19, 20: Truwit discloses of the above introducer device where the first and/or second locating attachment(s) is(are) frameless and interface to the surgeon via interface to control the trajectory of the guided medical/surgical device (col. 24, lines 24-52).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Truwit* as applied to claim 13 above, and further in view of *Lee et al* (US 3,893,449).

Truwit substantially discloses of all claimed invention in claim 15. Lee et al further discloses of medical imaging and invasive medical device alignment system such as Truwit can utilize potentiometer as a local position sensor (col. 1, line 64 – col. 2, line 11). Therefore, it

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would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Truwit to the teachings of Lee et al to achieve the claimed invention.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rapoport (US 5,957,934), ***Truwit et al*** (US 6,195,577), and ***Bova et al*** (US 6,546,279)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung whose telephone number is 703-605-4364. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on 703-305-3256. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

WCT

September 26, 2003


DENNIS RUHL
PRIMARY EXAMINER